

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D2097906	(X3) Date Survey Completed 11/18/2019
Name of Provider or Supplier Rapid Med Urgent Care The Colony	Street Address, City, State 3800 Main Street Suite 100, The Colony, TX	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D0000	Entrance and exit conferences were held with the laboratory technical consultants. The survey process was discussed and survey forms were provided. An opportunity for questions and comments was given. Noted deficiencies and plans of correction were discussed with the laboratory representatives at the entrance and exit conferences. The facility representatives were given an opportunity to provide evidence of compliance with the noted deficiency, and no such evidence was provided prior to survey exit. The facility was found to be in compliance with applicable Conditions of Participation in the CLIA program, and recertification is recommended. Note: The CMS-2567 (Statement of Deficiencies) is an official, legal document. All information must remain unchanged except for entering the plan of correction, correction dates, and the signature space. Any discrepancy in the original deficiency citation(s) will be reported to the Dallas Regional Office (RO) for referral to the Office of the Inspector General (OIG) for possible fraud. If information is inadvertently changed by the provider/supplier, the State Survey Agency (SA) should be notified immediately.
D5413	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b)</p> <p>The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.</p> <p>This STANDARD is not met as evidenced by: Based on review of Alere Triage D-Dimer and Cardiac Panel test device manufacturer's instructions, review of the laboratory's environmental monitoring</p>

records from 04/2019, 05/2019, and 08/2019, and staff interview, the laboratory failed to ensure room temperature ranges were within manufacturer's specifications prior to performing patient testing for 13 of 89 days. Findings included: 1. The manufacturer's instructions for Alere Triage test devices revealed the following: a. Alere Triage D-Dimer Test manufacturer's instructions (10002182-1 12/14) stated the following in the section titled "Storage Requirements": "Before using refrigerated Test Devices, allow individual foil pouches to reach operating temperature (20 - 24 C or 68 - 75F). This will take a minimum of 15 minutes." b. Alere Triage Cardiac Panel Test manufacturer's instructions (10002183-2 2/16) stated the following in the section titled "Storage Requirements": "Before using refrigerated Test Devices, allow individual foil pouches to reach operating temperature (20 - 24 C or 68 - 75F). This will take a minimum of 15 minutes." 2. A review of the laboratory's environmental monitoring records from 04/2019, 05/2019, and 08/2019 revealed the laboratory had an established an acceptable room temperature range for the laboratory of 18 - 25 C. The laboratory's acceptable room temperature range did NOT ensure temperature ranges were within manufacturer's specifications (20 -24 C) for the Alere Triage test devices. 3. Further review of the laboratory's environmental monitoring records from 04/2019, 05/2019, and 08/2019 revealed the following 13 of 89 days when the temperature was out of the acceptable range of 20 - 24 C: Date: 04/04/2019; Temperature: 26 C Date: 04/10/2019; Temperature: 25 C Date: 04/11/2019; Temperature: 25 C Date: 04/12/2019; Temperature: 25 C Date: 04/13/2019; Temperature: 25 C Date: 04/14/2019; Temperature: 25 C Date: 04/16/2019; Temperature: 25 C Date: 05/01/2019; Temperature: 25 C Date: 05/03/2019; Temperature: 25 C Date: 05/29/2019; Temperature: 25 C Date: 08/28/2019; Temperature: 25 C Date: 08/29/2019; Temperature: 25 C Date: 08/30/2019; Temperature: 25 C 3. An interview with TC #2 on 11/18/2019 at 1130 hours in the breakroom confirmed the findings.

D5421

ESTABLISHMENT AND VERIFICATION OF PERFORMANCE
CFR(s): 493.1253(b)(1)

Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population.

This STANDARD is not met as evidenced by:

Based on review of the laboratory's verification studies for the Clinical Diagnostic Solutions Medonic hematology analyzer (Serial Number 24723CD), and staff interview, it was revealed the laboratory failed to have documentation of verifying pediatric reference ranges (normal values) for the laboratory's pediatric population. Findings included: 1. Review of the verification studies form titled "Procedure for Performing the Optional Reference Range Study" for the Medonic hematology analyzer revealed the laboratory tested 20 normal, healthy adults to verify Complete Blood Count (CBC) reference ranges. 2. In an interview on 11/18/2019 at 1130 hours in the breakroom, Technical Consultant (TC)#1 was asked if the laboratory performed CBC's on pediatric patients. She replied that the laboratory did have pediatric patients but not very often. TC#1 was asked to provide verification studies for pediatric CBC reference ranges. She stated the laboratory performed verification studies for

reference ranges on 20 healthy adults. No documentation was provided for pediatric CBC reference ranges. This confirmed the above findings.